

REMARKS

Claims 1-12 and 29 remain in this application. New claims 30-32 are presently added. Claims 1, 3-5, 11, and 29 are presently amended. Reconsideration of this application in light of the foregoing amendments and the following remarks is requested.

A telephone interview was conducted between David O'Dell and David Hofman, attorneys for Applicants, and Examiner Davis on Wednesday, February 11, 2004. No specific claim was discussed, although the general subject matter of the pending claims and several proposed claim amendments were discussed. The Alaybayoglu, Palm, and Walker patents were also discussed. The Examiner indicated that claims directed to a surgical drill having a disposable battery pack may be allowable.

Rejections Under 35 U.S.C. §103

Claims 1-4

Claim 1, as presently amended, recites:

1. A surgical instrument comprising:
 - (a) a handpiece having a tool supporting end, and a battery receiving end, the battery receiving end having:
 - a first set of substantially concentrically arranged electrical contacts; and
 - first and second opposing flanges substantially perpendicular to and opposing a longitudinal axis of the handpiece and separated by first and second gaps of substantially different widths opposing the longitudinal axis; and
 - (b) a sterile package comprising a single surgical use, disposable battery pack having an attachment end, the attachment end having:
 - a second set of substantially concentrically arranged electrical contacts; and
 - third and fourth flanges opposing the handpiece longitudinal axis, substantially parallel to and slidably

engaged with the first and second opposing flanges, and configured to pass through a corresponding one of the first and second gaps in a single, predetermined relative position;

(c) wherein the two sets of contacts are adapted to become lockingly and conductively interengaged upon engagement of each of the third and fourth flanges with a corresponding one of the first and second flanges in response to rotation of the battery pack relative to the handpiece.

Claims 1 and 4 were rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 3,550,280 to Palm ("Palm") in view of U.S. Patent No. 4,823,244 to Alaybayoglu ("Alaybayoglu"). Claims 2 and 3 were also rejected under 35 U.S.C. § 103 as being unpatentable over Palm in view of Alaybayoglu and further in view of allegedly admitted prior art ("AAPA"). Applicants traverse these rejections on the grounds that these references are defective in establishing a *prima facie* case of obviousness with respect to claim 1.

As the PTO recognizes in MPEP § 2142:

... The Examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness. If the Examiner does not produce a prima facie case, the applicant is under no obligation to submit evidence of nonobviousness...

It is submitted that, in the present case, the Examiner has not factually supported a *prima facie* case of obviousness for the following, mutually exclusive, reasons.

1. Even When Combined, the References Do Not Teach the Claimed Subject Matter

The Palm and Alaybayoglu patents and the AAPA cannot be applied to reject claim 1 under 35 U.S.C. § 103 which provides that:

A patent may not be obtained ... if the differences between the

subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains ... (Emphasis added)

Thus, when evaluating a claim for determining obviousness, all limitations of the claim must be evaluated. However, neither Palm, Alaybayoglu, nor AAPA teach a handpiece receiving end having "... first and second opposing flanges substantially perpendicular to and opposing a longitudinal axis of the handpiece and separated by first and second gaps of substantially different width opposing the longitudinal axis ...," as is claimed in claim 1. Palm, Alaybayogly, and AAPA also fail to teach a disposable battery pack attachment end having "... third and fourth flanges opposing the handpiece longitudinal axis, substantially parallel to and slidably engaged with the first and second opposing flanges, and configured to pass through a corresponding one of the first and second gaps in a single, predetermined relative position ...," as is claimed in claim 1. Palm, Alaybayogly, and AAPA also fail to teach two sets of contacts "... adapted to become lockingly and conductively interengaged upon engagement of each of the third and fourth flanges with a corresponding one of the first and second flanges in response to rotation of [a] battery pack relative to the handpiece ...," as is claimed in claim 1. Consequently, it is impossible to render the subject matter of claim 1 as a whole obvious, and the explicit terms of the statute cannot be met.

Thus, for this mutually exclusive reason, the Examiner's burden of factually supporting a *prima facie* case of obviousness has clearly not been met, and the rejection of claim 1 under 35 U.S.C. §103 should be withdrawn.

2. Nonanalogous art cannot be used to establish obviousness

The Palm patent relates to "electric hair clippers for home or professional use in cutting human hair." (Column 1, lines 23-25). However, the Alaybayoglu patent is related to light

sources for medical applications. (Column 1, lines 4-29). 35 U.S.C. §103 requires that obviousness be determined on the basis of whether at the time the invention was made a person of ordinary skill in the art to which the subject matter pertains would have found the claimed invention as a whole obvious. Although one of ordinary skill in the art is presumed to be aware of all prior art in the field to which the invention pertains, he is not presumed to be aware of prior art outside that field and the field of the problem to be solved, *i.e.*, nonanalogous art.

Accordingly, in assessing the propriety of any assertion of prior art as a basis for a *prima facie* case of obviousness, one must determine the scope or bounds of the knowledge of one of ordinary skill in the art, *i.e.*, the analogous art presumably known by one of ordinary skill in the art.

Here, since human hair clippers are clearly outside the field of light sources for medical equipment, and since commercial hair clippers are clearly outside the field of any medical equipment, the cited references are from nonanalogous art, thus precluding any *prima facie* case of obviousness.

Thus, for this independent reason alone, the Examiner's burden of factually supporting a *prima facie* case of obviousness has clearly not been met, and the rejection of claim 1 under 35 U.S.C. §103 should be withdrawn.

3. The Combination of References is Improper

Assuming, *arguendo*, that none of the above arguments for non-obviousness apply (which is clearly not the case based on the above), there is still another, mutually exclusive, and compelling reason why the Palm and Alaybayoglu patents cannot be applied to reject claim 1 under 35 U.S.C. § 103.

§ 2142 of the MPEP also provides:

...the Examiner must step backward in time and into the shoes worn by the hypothetical 'person of ordinary skill in the art' when the invention was unknown and just before it was made.....The Examiner must put aside knowledge of the applicant's disclosure, refrain from using hindsight, and consider the subject matter claimed 'as a whole'.

Here, neither Palm, Alaybayoglu, nor AAPA teaches, or even suggests, the desirability of the combination since neither teaches:

- a handpiece receiving end having “... first and second opposing flanges substantially perpendicular to and opposing a longitudinal axis of the handpiece and separated by first and second gaps of substantially different width opposing the longitudinal axis ...,”
- a disposable battery pack attachment end having “... third and fourth flanges opposing the handpiece longitudinal axis, substantially parallel to and slidably engaged with the first and second opposing flanges, and configured to pass through a corresponding one of the first and second gaps in a single, predetermined relative position ...,” and
- two sets of contacts “... adapted to become lockingly and conductively interengaged upon engagement of each of the third and fourth flanges with a corresponding one of the first and second flanges in response to rotation of [a] battery pack relative to the handpiece ...,”

as is claimed in claim 1.

Thus, it is clear that neither reference provides any incentive or motivation supporting the desirability of the combination. Therefore, there is simply no basis in the art for combining the references to support a 35 U.S.C. § 103 rejection.

In this context, the MPEP further provides at § 2143.01:

The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination.

In the above context, the courts have repeatedly held that obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination.

In the present case it is clear that the Examiner's combination arises solely from hindsight based on the invention without any showing, suggestion, incentive, or motivation in either reference for the combination as applied to claim 1. Moreover, in light of the extreme degree to which Palm and Alaybayoglu are non-analogous art from clearly disparate technological fields, as discussed above, the fact that neither reference provides any showing, suggestion, incentive, or motivation for combination is merely logical. Therefore, for this mutually exclusive reason, the Examiner's burden of factually supporting a *prima facie* case of obviousness has clearly not been met, and the rejection of claim 1 under 35 U.S.C. §103 should be withdrawn.

Claims 2-4 depend from and further limit independent claim 1. Therefore, any combination of Palm, Alaybayoglu, and AAPA also fails to support a rejection of claims 2-4 under 35 U.S.C. §103. Consequently, these rejections should also be withdrawn.

New claim 32 also depends from and further limits independent claim 1. Therefore, any combination of Palm, Alaybayoglu, and AAPA also fails to support a rejection of claim 32 under 35 U.S.C. §103.

Claims 5-10

Claim 5, as presently amended, recites:

5. A surgical instrument for performing a cutting, shaping, or drilling operation on live human bone or hard tissue, comprising:

(a) a handpiece having a battery receiving end with an alignment post extending therefrom and a tool supporting end for supporting a tool for performing a cutting, shaping, or drilling operation on live human bone or hard tissue; and

(b) a sterile package containing a single use, disposable battery pack which has an attachment end with a central opening therein;

(c) the central opening in the single use, disposable battery pack being adapted to insertably receive the alignment post so as to establish a mutual alignment axis of handpiece and battery pack;

(d) the battery receiving end of the handpiece and the attachment end of the single use, disposable battery pack having flat end surfaces adapted for abutting engagement while yet allowing relative rotation of the battery pack relative to the handpiece;

(e) the battery receiving end of the handpiece and the attachment end of the single use, disposable battery pack having mating sets of electrical contact elements, each set being arranged generally concentric to the mutual alignment axis; and

(f) wherein upon the insertion of the alignment post of the handpiece into the opening of the battery pack, the sets of mating contacts are adapted to then become lockingly and conductively interengaged in response to rotation of the battery pack relative to the handpiece.

Claims 5, 7, and 8 were rejected under 35 U.S.C. § 103 as being unpatentable over Palm in view of Alaybayoglu. Claim 6 was also rejected under 35 U.S.C. § 103 as being unpatentable over Palm in view of Alaybayoglu and further in view of AAPA. Claims 9 and 10 were also rejected under 35 U.S.C. § 103 as being unpatentable over Palm in view of Alaybayoglu and further in view of U.S. Patent No. 5,368,954 to Bruns ("Bruns"). Applicants traverse these rejections on the grounds that these references are defective in establishing a *prima facie* case of obviousness with respect to claims 5-10. It is submitted that the Examiner has not factually supported a *prima facie* case of obviousness for the following, mutually exclusive, reasons.

1. Even When Combined, the References Do Not Teach the Claimed Subject Matter

Neither Palm, Alaybayoglu, nor Bruns teach “a surgical instrument for performing a cutting, shaping, or drilling operation on live human bone or hard tissue,” as is claimed in claim 5. Palm, Alaybayogly, and Bruns also fail to teach “a tool supporting end for supporting a tool for performing a cutting, shaping, or drilling operation on live human bone or hard tissue,” as is claimed in claim 5. Palm, Alaybayogly, and Bruns also fail to teach “flat end surfaces adapted for abutting engagement,” as is claimed in claim 5. Consequently, it is impossible to render the subject matter of claim 5 as a whole obvious, and the explicit terms of the statute cannot be met.

The Examiner asserted that Palm discloses in Fig. 10 that the handpiece 16 has flat end surfaces 76 which abut against flat surfaces of element 126 of the battery pack. (Examiner’s Office Action, page 3). However, the embodiment to which the Examiner refers includes rechargeable batteries that are rechargeable by placing the entire clipper unit in a charging stand 141. (Col. 11, lines 57-75). Thus, one skilled in the art would not look to this embodiment for motivation or suggestion (or find such motivation or suggestion therein) of a detachable battery pack, because the battery pack of this embodiment is permanently affixed and rechargeable without removal. Moreover, the flat end surfaces 76 to which the Examiner refers are not flat end surfaces. Furthermore, what is actually referred to in Palm as a “cover 76” does not have external-facing surfaces for abutting with flat end surfaces of the opposing housing unit 16. In contrast, the abutting surfaces to which the Examiner refers (cover 76 and cover 126) are both located internal to the permanently attached rear housing 123. Thus, not only are the surfaces to which the Examiner refers not flat end surfaces, they are also not abutting surfaces of separate housing units.

Thus, for this mutually exclusive reason, the Examiner's burden of factually supporting a *prima facie* case of obviousness has clearly not been met, and the rejection of claim 5 under 35 U.S.C. §103 should be withdrawn.

2. Nonanalogous art cannot be used to establish obviousness

As described above, Palm and Alaybayoglu are from nonanalogous art, thus precluding any *prima facie* case of obviousness based on any combination including Palm and Alaybayoglu. That is, the addition of Bruns does not correct the impropriety of the combination of Palm and Alaybayoglu. Thus, for this independent reason alone, the Examiner's burden of factually supporting a *prima facie* case of obviousness has clearly not been met, and the rejection of claim 5 under 35 U.S.C. §103 should be withdrawn.

3. The Combination of References is Improper

Assuming, arguendo, that none of the above arguments for non-obviousness apply (which is clearly not the case based on the above), there is still another, mutually exclusive, and compelling reason why the Palm, Alaybayoglu and Bruns patents cannot be applied to reject claim 5 under 35 U.S.C. § 103.

As described above, § 2142 of the MPEP requires the Examiner to step backward in time and into the shoes worn by the hypothetical 'person of ordinary skill in the art' when the invention was unknown and just before it was made, refrain from using hindsight, and consider the subject matter claimed 'as a whole'. However, neither Palm, Alaybayoglu, nor Bruns teaches, or even suggests, the desirability of the combination since neither teaches:

- “a surgical instrument for performing a cutting, shaping, or drilling operation on live human bone or hard tissue,”
- “a tool supporting end for supporting a tool for performing a cutting, shaping, or drilling operation on live human bone or hard tissue,” and
- “flat end surfaces adapted for abutting engagement,”

as is claimed in Claim 5.

Thus, it is clear that none of the references provide any incentive or motivation supporting the desirability of the combination. Therefore, there is simply no basis in the art for combining the references to support a 35 U.S.C. § 103 rejection. As also discussed above, the courts have repeatedly held that obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination. In the present case it is clear that the Examiner’s combination arises solely from hindsight based on the invention without any showing, suggestion, incentive, or motivation in either reference for the combination as applied to claim 5. Therefore, for this mutually exclusive reason, the Examiner’s burden of factually supporting a *prima facie* case of obviousness has clearly not been met, and the rejection of claim 5 under 35 U.S.C. §103 should be withdrawn.

Claims 6-10 depend from and further limit independent Claim 5. Therefore, any combination of Palm, Alaybayoglu, and Bruns also fails to support a rejection of claims 6-10 under 35 U.S.C. §103. Consequently, these rejections should also be withdrawn.

Claims 11 and 12

Claim 11, as presently amended, recites:

11. A surgical instrument for performing a surgical drilling procedure on bone or hard tissue, comprising:

(a) a handpiece having a rotary driven drilling member supported by a tool supporting end, and a battery receiving end with an alignment post extending therefrom, the battery receiving end of the handpiece also having a set of electrical contact elements arranged in generally concentric relation to the alignment post;

(b) a disposable battery having an attachment end with a central opening therein, and a set of mating electrical contact elements arranged in a generally circular configuration concentric to the central opening therein;

(c) the central opening in the disposable battery being adapted to receive the alignment post of the handpiece in a partially inserted position so as to establish a pre-attachment alignment thereof;

(d) the sets of mating contacts being adapted to come into a mutually concentric relation in response to a further insertion of the alignment post into the central opening; and

(e) the sets of contacts being adapted to then become lockingly and conductively interengaged upon rotation of the battery pack relative to the handpiece.

Claim 11 was rejected under 35 U.S.C. § 103 as being unpatentable over Palm in view of Alaybayoglu. Claim 12 was also rejected under 35 U.S.C. § 103 as being unpatentable over Palm in view of Alaybayoglu and further in view of AAPA. Applicants traverse these rejections on the grounds that these references are defective in establishing a *prima facie* case of obviousness with respect to claims 11 and 12. It is submitted that, in the present case, the Examiner has not factually supported a *prima facie* case of obviousness for the following, mutually exclusive, reasons.

1. Even When Combined, the References Do Not Teach the Claimed Subject Matter

Neither Palm, Alaybayoglu, nor AAPA teach “a surgical instrument for performing a surgical drilling procedure on bone or hard tissue,” as is claimed in claim 11. Palm, Alaybayoglu, and AAPA also fail to teach “a handpiece having a rotary driven drilling member supported by a tool supporting end,” as is claimed in claim 11. Consequently, it is impossible to render the subject matter of claim 11 as a whole obvious, and the explicit terms of the statute cannot be met.

The Examiner asserts that because Palm’s clippers could be used to cut bone, and because tools intended for commercial use may also be used in surgery, then Palm’s clippers may be considered a surgical tool. (Examiner’s Office Action, pages 3 and 4). However, the Applicants disagree that Palm’s clippers could be used to cut bone, and invite the Examiner to direct Applicants’ attention to a reference describing such bone-cutting hair clippers. Such application is clearly absent from the Palm disclosure.

Similarly, most tools intended for commercial are not used or able to be used during surgical operations. The Applicants also invite the Examiner to provide a reference supporting his premise that tools intended for commercial use may also be used in surgery. While it is true that surgical instruments may be used in non-surgical, “commercial” applications, the Examiner has failed to demonstrate that the reverse is true.

Thus, for this mutually exclusive reason, the Examiner’s burden of factually supporting a *prima facie* case of obviousness has clearly not been met, and the rejection of claim 11 under 35 U.S.C. §103 should be withdrawn.

2. Nonanalogous art cannot be used to establish obviousness

As described above, Palm and Alaybayoglu are from nonanalogous art, thus precluding any *prima facie* case of obviousness based on any combination including Palm and Alaybayoglu.

Thus, for this independent reason alone, the Examiner's burden of factually supporting a *prima facie* case of obviousness has clearly not been met, and the rejection of claim 11 under 35 U.S.C. §103 should be withdrawn.

3. The Combination of References is Improper

As described above, § 2142 of the MPEP requires the Examiner to step backward in time and into the shoes worn by the hypothetical 'person of ordinary skill in the art' when the invention was unknown and just before it was made, refrain from using hindsight, and consider the subject matter claimed 'as a whole'. However, neither Palm, Alaybayoglu, nor AAPA teaches, or even suggests, the desirability of the combination since neither teaches:

- “a surgical instrument for performing a cutting, shaping, or drilling operation on live human bone or hard tissue,” and
- “a tool supporting end for supporting a tool for performing a cutting, shaping, or drilling operation on live human bone or hard tissue,”

as is claimed in Claim 11.

Thus, it is clear that none of the references provide any incentive or motivation supporting the desirability of the combination. Therefore, there is simply no basis in the art for combining the references to support a 35 U.S.C. § 103 rejection. As also discussed above, the courts have repeatedly held that obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination. In the present case it is clear that the Examiner's combination arises solely from hindsight based on the invention without any showing, suggestion, incentive, or motivation in either reference for the combination as applied to claim 11. Therefore, for this mutually exclusive reason, the Examiner's burden of factually supporting a *prima facie* case of

obviousness has clearly not been met, and the rejection of claim 11 under 35 U.S.C. §103 should be withdrawn.

Claim 12 depends from and further limits independent claim 11. Therefore, any combination of Palm, Alaybayoglu, and AAPA also fails to support a rejection of claim 12 under 35 U.S.C. §103. Consequently, this rejection should also be withdrawn.

Claims 29-32

Claim 29, as presently amended, recites:

29. A surgical instrument for removing live human bone or hard tissue, comprising:
a handpiece including:
a first end supporting a rotary driven tool configured to remove live human bone or hard tissue by rotation of a cutting member in response to rotary drive means within the handpiece; and
a second end having:
an alignment post extending therefrom and defining a handpiece longitudinal axis; and
a plurality of handpiece electrical contacts arranged concentric to the handpiece longitudinal axis; and
a sterile, disposable battery pack including:
lithium/manganese dioxide batteries; and
an attachment end configured to be secured to the handpiece second end by means of a rotating movement of the disposable battery pack relative to the handpiece, the attachment end having:
an opening therein defining a battery pack longitudinal axis; and
a plurality of battery pack electrical contacts arranged concentric to the battery pack longitudinal axis; wherein
the attachment end opening is configured to receive the

handpiece alignment post so as to establish a mutual alignment axis between the handpiece longitudinal axis and the battery pack longitudinal axis; and

the pluralities of the handpiece and battery pack contacts are mating pluralities of contacts configured to be lockingly and conductively interengaged in response to the rotating movement.

Claim 29 was rejected under 35 U.S.C. § 103 as being unpatentable over the combination of Palm, Alaybayoglu, Bruns and AAPA. Applicants traverse this rejection on the grounds that these references are defective in establishing a *prima facie* case of obviousness with respect to claims 29. It is submitted that the Examiner has not factually supported a *prima facie* case of obviousness for the following, mutually exclusive, reasons.

1. Even When Combined, the References Do Not Teach the Claimed Subject Matter

Neither Palm, Alaybayoglu, Bruns nor AAPA teach “a surgical instrument for removing live human bone or hard tissue,” as is claimed in claim 29. Palm, Alaybayoglu, Bruns and AAPA also fail to teach “a first end supporting a rotary driven tool configured to remove live human bone or hard tissue by rotation of a cutting member in response to rotary drive means within the handpiece,” as is claimed in claims 29. Consequently, it is impossible to render the subject matter of claim 29 as a whole obvious, and the explicit terms of the statute cannot be met.

Thus, for this mutually exclusive reason, the Examiner’s burden of factually supporting a *prima facie* case of obviousness has clearly not been met, and the rejection of claim 29 under 35 U.S.C. §103 should be withdrawn.

2. Nonanalogous art cannot be used to establish obviousness

As described above, Palm and Alaybayoglu are from nonanalogous art, thus precluding any *prima facie* case of obviousness based on any combination including Palm and Alaybayoglu. That is, the addition of Bruns and AAPA fails to correct the impropriety of the combination of Palm and Alaybayoglu. Thus, for this independent reason alone, the Examiner's burden of factually supporting a *prima facie* case of obviousness has clearly not been met, and the rejection of claim 29 under 35 U.S.C. §103 should be withdrawn.

3. The Combination of References is Improper

As described above, § 2142 of the MPEP requires the Examiner to step backward in time and into the shoes worn by the hypothetical 'person of ordinary skill in the art' when the invention was unknown and just before it was made, refrain from using hindsight, and consider the subject matter claimed 'as a whole'. However, neither Palm, Alaybayoglu, nor AAPA teaches, or even suggests, the desirability of the combination since neither teaches:

- “a surgical instrument for removing live human bone or hard tissue,” and
- “a first end supporting a rotary driven tool configured to remove live human bone or hard tissue by rotation of a cutting member in response to rotary drive means within the handpiece,”

as is claimed in Claim 29.

Thus, it is clear that none of the references provide any incentive or motivation supporting the desirability of the combination. Therefore, there is simply no basis in the art for combining the references to support a 35 U.S.C. § 103 rejection. As also discussed above, the courts have repeatedly held that obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination. In the present case it is clear that the Examiner's combination arises

solely from hindsight based on the invention without any showing, suggestion, incentive, or motivation in either reference for the combination as applied to claim 29. Therefore, for this mutually exclusive reason, the Examiner's burden of factually supporting a *prima facie* case of obviousness has clearly not been met, and the rejection of claim 29 under 35 U.S.C. §103 should be withdrawn.

New claims 30 and 31 depend from and further limit independent claim 29. Therefore, any combination of Palm, Alaybayoglu, Bruns, and AAPA also fails to support a rejection of claims 30 and 31 under 35 U.S.C. §103.

Conclusion

It is clear from all of the foregoing that claims 1-12 and 29-32 are in condition for allowance. An early formal notice of allowance of claims 1-12 and 29-32 is therefore requested.

Respectfully submitted,



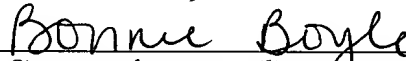
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